

Remarks/Arguments

Status of the Claims

Upon entry of the foregoing amendments, claims 1 to 7 will be pending in this patent application. Claims 8 to 12 have been canceled, without prejudice. Claims 1, 2 and 7 have been amended, without prejudice.

In view of the foregoing amendments and the following remarks, reconsideration and withdrawal of the rejections are respectfully requested.

Discussion of the Rejections under 35 U.S.C. § 112

Claims 1 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. (Action at 2 to 3). Applicants respectfully traverse this rejection.

Claim 1 is rejected as allegedly indefinite with regard to the term "pharmaceutically acceptable carrier." Although Applicants respectfully disagree, claim 1 has been amended, without prejudice, to delete such term thereby rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Claim 1 is also rejected as allegedly indefinite with regard to the phrase "provided that the unsubstituted benzo[1,3]dioxole is excluded". Although Applicants respectfully disagree, claim 1 has been amended, without prejudice, to specify that this recitation is applicable to the substituent Het. Applicants submit that such amendment renders the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Claim 7 is rejected as allegedly indefinite with regard to whether such claim is directed to a process or a method of use. Although Applicants respectfully disagree, claim 7 has been amended, without prejudice, to specify that such claim is a method of use type claim. Applicants submit that such amendment renders the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Claims 7 to 12 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement with regard to the treatment of all diseases recited in such claims (Action at 3 to 9). Although Applicants respectfully disagree, claims 8 to 12 have been canceled and claim 7 has been amended to recite that the disease treated is osteoarthritis. Applicants submit that such amendments render the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Discussion of the Rejections under 35 U.S.C. § 102(b)

Claims 1 to 3 and 5 to 12 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by International Application Publication No. WO02/064571 to Barvian et al. (hereinafter "Barvian"). (Action at 9). Applicants respectfully traverse this rejection in view of pending Claims 1 to 3 and 5 to 7 as Barvian does not teach or suggest Applicants' claimed invention for at least the following reasons.

In the first instance, Applicants note that Barvian is incorrectly characterized as prior art available under 35 U.S.C. 102(b). The present application, which claims priority to U.S. Provisional Application Nos. 60/456,395 and 60/458,316, has an effective filing date of March 21 and 28, 2003. As Barvian was published on August 22, 2002, it is not available under 102(b) as it was published *less than one year* before the earliest filing date to which the present application claims priority. Applicants do not concede that Barvian is prior art to the invention as now claimed. Applicants hereby reserve the right to swear behind this patent at a later time.

Applicants, however, assert that the claimed invention is nevertheless patentably distinct over the disclosure of Barvian for at least the following reason. Barvian *does not* disclose the instant compounds at least where R2 is -(C<sub>1</sub>-C<sub>6</sub>)-alkyl, wherein alkyl is substituted one, two or three times as recited in, for example, claim 1. Although the Examiner asserts that various species of the instant compounds are disclosed on pages 5 to 7 of Barvian, (Action at 9), the 18 compounds recited therein *do not* include any of the compounds of the present invention. For example, Barvian at page 5 discloses the compound pyrimidine-4,6-dicarboxylic acid, (4-chloro-benzylamide), [(1,3-benzodioxol-5-ylmethyl)-amide]. The [(1,3-benzodioxol-5-ylmethyl)-amide] portion of such compound corresponds to the R2 of the instant compounds where -(C<sub>1</sub>-C<sub>6</sub>)-alkyl- is substituted one time by 4. -(C<sub>6</sub>-C<sub>14</sub>)-aryl. 4. -(C<sub>6</sub>-C<sub>14</sub>)-aryl, however, is substituted itself one, two or three times with the specific substituents recited in claim 1. As the recited substituents of 4. -(C<sub>6</sub>-C<sub>14</sub>)-aryl *do not* include -C(O)-, such compound does not fall within the general formula of the instantly claimed compounds. Thus, for at least this reason, Applicants submit respectfully that Barvian does not anticipate the claimed invention. Accordingly, reconsideration and withdrawal of the rejection is requested respectfully.

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Claims 1 to 3, 5 and 6 are also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,130,317 to Baader et al. (hereinafter "Baader"). (Action at 9). Applicants respectfully traverse this rejection as the claimed invention is patentably distinct over the disclosure of Baader for at least the following reason.

Baader *does not* disclose the instant compounds at least where R2 is -(C<sub>1</sub>-C<sub>6</sub>)-alkyl, wherein alkyl is substituted one, two or three times as recited in claim 1. The Examiner asserts that Baader discloses compounds that fall within the general formula of the presently claimed compounds where R2 is substituted with phenyl or Het as can be seen when the R1 of Baader is alkyl substituted with phenyl or indolyl. (Action at 10). In the first instance, substituents 4.34 and 4.35 can be selected such that R2 is -(C<sub>1</sub>-C<sub>6</sub>)-alkyl substituted one, two or three times by 4. -(C<sub>6</sub>-C<sub>14</sub>)-aryl, which is itself substituted one, two or three times by 4.34 -(C<sub>0</sub>-C<sub>4</sub>)-alkyl-Het or 4.35 -phenyl. Baader, however, discloses a compound where R1 is -(C<sub>1</sub>-C<sub>12</sub>)-alkyl which may be substituted with phenyl or indolyl, which itself may be substituted with *halogen, nitro, (C<sub>1</sub>-C<sub>4</sub>)-alkyl or (C<sub>1</sub>-C<sub>4</sub>)-alkoxy* (see Col. 2, lines 1 to 35). As the recited substituents of 4. -(C<sub>6</sub>-C<sub>14</sub>)-aryl *do not* include halogen, nitro, (C<sub>1</sub>-C<sub>4</sub>)-alkyl or (C<sub>1</sub>-C<sub>4</sub>)-alkoxy, the compounds disclosed in Baader *do not* fall within the general formula of the instantly claimed compounds. Thus, for at least this reason, Applicants submit respectfully that Barvian does not anticipate the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

#### Discussion of the Rejections under 35 U.S.C. § 103(a)

Claims 1 to 12 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barvian. (Action at 11). Applicants respectfully traverse this rejection as Barvian does not teach or suggest the presently claimed invention.

As detailed above, Barvian does not disclose the compounds of the present invention such as, for example, where R2 is -(C<sub>1</sub>-C<sub>6</sub>)-alkyl, wherein alkyl is substituted one, two or three times as recited in claim 1. Further, there is no suggestion in Barvian that would motivate one of ordinary skill in the art to modify Barvian in order to produce the presently claimed invention. The Examiner contends that modification of Barvian is suggested by virtue of the fact that Barvian allegedly discloses *species* of compounds that fall within the presently claimed generic formula. As noted above, however, Barvian *does not* disclose compounds that fall within the

presently claimed generic formula. The Action does not provide evidence of any suggestion present in the disclosure of Barvian, as it must, that would motivate one of ordinary skill in the art to modify Barvian to produce the presently claimed invention. In fact, the disclosure of Barvian as a whole *does not* disclose or suggest any of the presently claimed compounds. Thus, for at least this reason, Applicants submit respectfully that the claimed invention is patentable over Barvian. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Claims 1 to 12 are also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baader (Action at 11 to 12). Applicants respectfully traverse this rejection as Baader does not teach or suggest the presently claimed invention.

As detailed above, Baader does not disclose the compounds of the present invention such as, for example, where R2 is -(C<sub>1</sub>-C<sub>6</sub>)-alkyl, wherein alkyl is substituted one, two or three times as recited in claim 1. Further, there is no suggestion in Baader that would motivate one of ordinary skill in the art to modify Baader in order to produce the presently claimed invention. The Examiner contends that modification of Baader is suggested by virtue of the fact that Baader allegedly discloses *species* of compounds that fall within the presently claimed generic formula. As noted above, however, Baader *does not* disclose compounds that fall within the presently claimed generic formula. Moreover, the Action does not provide evidence of any suggestion present in the disclosure of Baader, as it must, that would motivate one of ordinary skill in the art to modify Baader to produce the presently claimed invention. In fact, the disclosure of Baader as a whole does not disclose or suggest any of the presently claimed compounds. Thus, for at least this reason, Applicants submit respectfully that the claimed invention is patentable over Baader. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

#### **Discussion of the Double Patenting Rejection**

Claims 1 to 12 are rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 to 17 of U.S. Patent No. 6,913,298 to Weithmann et al. (Action at 12 to 13). Applicants request that this rejection be deferred pending some identification of allowable subject matter, as it likely can be readily resolved (depending upon the subject matter ultimately allowed) through the filing of a suitable terminal disclaimer.

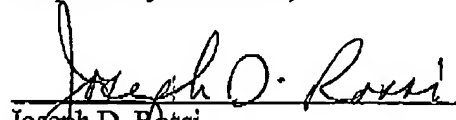
**Conclusion**

Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited to call the undersigned attorney at (908) 231-3410.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

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